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09/941,970	08/29/2001	Ashok Rampal	RLL-170US	7742

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EXAMINER	
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ART UNIT	PAPER NUMBER
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/941,970
Filing Date: August 29, 2001
Appellant(s): RAMPAL ET AL.

William D. Hare
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/26/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1,2 and 5-12 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 00/15198	TALWAR et al	03-2000
5,518,730	FUISZ	05-1996
5,869,098	MISRA et al	02-1999
6,096,339	AYER et al	08-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1,2 and 5-12 were rejected under 35 U.S.C. 103 (a). This rejection is set forth in a prior Office Action, mailed on 08/19/2003.

(11) Response to Argument

Applicant argues that claims 1,2 and 5-12 are unobvious over the combination of the prior art because of the following points:

a. The art of record does not describe or suggest between about 0.1% w/w to about 4%w/w of rate controlling polymers

Regarding this argument, it is the position of the examiner that the prior art does in fact teach this limitation. Claim 1 recites "[a] controlled release formulation...comprises...from about 0.1% to about 4% of one or more pharmaceutical acceptable... polymer." Given the broadest reasonable interpretation of the claim, it is the position of the examiner that only one pharmaceutical acceptable polymer in a given formulation must be present in the concentrations listed. As seen in Talwar et al, the formulation comprising between 0.5% to about 5% w/w of hydrophilic polymers such as hydroxypropylcellulose and Carbopol (pg. 20, lin. 19- pg. 21 lin. 7). Talwar et al also discloses that the viscolyzing agents such as xanthan gum must be kept to a

very low percentage (below 3%) in order to maintain the controlled release of the dosage form (pg. 17, lin. 15 – pg. 18, lin. 2). These percentages are exemplified in Table 3, of Example 2 (pg. 23, lin. 1 – 27) where the xanthan gum and sodium alginate are well below 3% (see figure below).

TABLE 3

Ingredient	Weight (mg/tablet)	% w/w of tablet	% w/w of drug
Ciprofloxacin base	1000.00	71.43	100.0
Xanthan Gum (Keltrol TF)	15.00	1.07	1.5
Sodium alginate (Keltone LVCR)	10.00	0.71	1.0
Cross-linked polyvinylpyrrolidone (Kollidon CL-M)	150.00	10.71	15.0
Sodium bicarbonate	200.00	14.28	20.0
Magnesium Stearate	15.00	1.07	1.5
Talc	10.00	0.71	10.0
Total	1400.00	100	--

For these reasons alone the Talwar reference obviates the limitation of rate controlling polymers present in a concentration from about 0.1% to about 4% w/w.

b. The art of record does not describe or suggest between about 66% w/w to about 90% w/w of erythromycin A or a derivative

Regarding this argument, it is also the position of the examiner that Talwar et al again provides sufficient suggestion and enabling disclosures to obviate the instant invention, specifically the limitation reciting the concentration of active agents. The examiner agrees that Talwar does not exemplify a clarithromycin formulation yet provides an enabling disclosure showing the equivalence of ciprofloxacin and clarithromycin (pg. 14, lin. 11- 13).

> **Illustrative examples of drugs that are suitable for the present invention include antibacterial/anti-infective agents, such as ciprofloxacin, cefuroxime, cefatrizine, cefpodoxime, clarithromycin, loracarbef, azithromycin, cefixime, cefadroxil, amoxycillin,**

As seen in Table 3, the antibacterial agent is present at a concentration of 71.43%, well within the limitations of the instant invention. It is the position of the examiner that Talwar et al provides sufficient enabling disclosures to allow a skilled artisan to substitute any of the listed antibacterial agents into the formulation exemplified by Table 3. For these reasons alone, the Talwar reference obviates the limitations of clarithromycin being present in a concentration between 66% w/w to about 90% w/w.

c. Independent claims 11 and 12 are allowable for the same reasons that claim 1 is allowable

Regarding this argument, it is the position of the examiner that these claims are no more patentable than claim 1 in view of the Talwar reference. As discussed above Talwar provides sufficient enabling disclosures to obviate the instant claims regarding the percentages of both the active agent and rate controlling polymers. To illustrate this point the examiner draws attention to applicant's Example 1, Table 1.1 (pg. 10, lin. 1-5)

Table 1.1

Ingredients	mg/tab	Percent w/w of tablet weight
Clarithromycin equivalent to	1000.0	81.0
Sodium Alginate (LVCR)	12.5	1.0
Xanthan Gum	37.5	3.0
Cross-linked polyvinylpyrrolidone (CL-PVP)	125.0	10.1
Magnesium Stearate	12.5	1.0
Talc	20.0	1.6
Sodium stearyl fumarate	20.0	1.6
Aerosil 200	8.0	0.70
Purified water	Qs	qs
Total weight	1235.5	100.0

This example is nearly identical to Table 3, of Example 2 of Talwar et al (pg. 23, lin. 1 – 27)

TABLE 3

Ingredient	Weight (mg/tablet)	% w/w of tablet	% w/w of drug
Ciprofloxacin base	1000.00	71.43	100.0
Xanthan Gum (Keltrol TF)	15.00	1.07	1.5
Sodium alginate (Keltone LVCR)	10.00	0.71	1.0
Cross-linked polyvinylpyrrolidone (Kollidon CL-M)	150.00	10.71	15.0
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Magnesium Stearate	15.00	1.07	1.5
Talc	10.00	0.71	10.0
Total	1400.00	100	--

Combined with the enabling disclosure of pg. 14, which establishes the equivalence between clarithromycin and ciprofloxacin, and the process as described on pg. 21 lin 19 – 22, lin. 4, which discloses steps of mixing the rate controlling polymers, along with the other components and formed into monolithic tablets, Talwar obviates the instantly claimed monolithic dosage form and process of preparing such a dosage form.

Regarding the supportive references, of Fuisz, Misra and Ayer, as discussed in the Final Office Action, mailed on 08/19/2003, these references are provided to show the level of skill in the art regarding the equality and substitutable relationship between ciprofloxacin and clarithromycin. Talwar remains the main reference of obviousness and contains the teachings and suggestions of the instant invention. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981);*In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Talwar establishes that ciprofloxacin and clarithromycin would work equally well in the formulation discloses in the examples, the supporting reference

reinforce the use of both compounds in similar formulation comprising rate controlling polymers such as Carbopol and hydroxypropylcellulose. For these reasons the claims remain obviated by the prior art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Examiner
Art Unit 1615

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June 24, 2004

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